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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,666	11/28/2000	Roman Sakowicz	UCSD-04873	9298

7590 10/14/2003

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EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/14/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

# Office Action Summary

Application N .

09/724,666

Applicant(s)

SAKOWICZ ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 58-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

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## **DETAILED ACTION**

### ***Amendment Entry***

1. The preliminary amendment filed November 12, 2002 has been entered. The examiner acknowledges the amendments to the specification. Claim 58 has been amended. Claims 59-77 have been newly added. Claims 58-77 are under consideration in this office action.

### ***Withdrawal of Rejections***

2. The following rejections have been withdrawn:

- a) the rejection of claim 58 under 35 U.S.C. 102(a) as being anticipated by Alphey et al.;
- b) the rejection of claim 58 under 35 U.S.C. 102(b) as being anticipated by Nangaku et al.; and
- c) the rejection of claim 58 under 35 U.S.C. 112 first paragraph.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 63-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. In particular claims 63 and 68 are drawn to using amino acids 1 to 357 and 443 to 601 of SEQ ID NO:1 in a method to identifying an agent that binds to said amino acids. Neither the specification nor originally presented claims provides support for using amino acids 1 to 357 and 443 to 601 of SEQ ID NO:1 to identify candidate agents. Applicants' support at pages 6,7,9 and 22 is drawn to the isolation of the recited amino acids or that amino acids 602 to 784 of SEQ ID NO:1 can identify polymorphic variants, orthologs, alleles and homologues of TL- $\gamma$  is made by comparing the amino acid sequence of the tail domain. However, there is no teaching about using amino acids 1 to 357 and 443 to 601 in an identification method. Applicants' did not point to support in the specification for a method to identifying an agent that binds to said amino acids. Thus, there appears to be no teaching of a method to identifying an agent that bind to said amino acids. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for method to identifying an agent which binds to said amino acids as recited by the newly added amendments. Therefore, the new claims incorporate new matter and are accordingly rejected.

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4. Claims 58-77 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims recite an incomplete method.

In particular, claims 58, 63, 68 and 73 are drawn to a method for identifying agents that bind to SEQ ID NO:1 or amino acids 1 to 357, 443 to 601 and 602 to 784 of SEQ ID NO:1. There is no step for contacting a sample comprising a candidate agent with an amino acid molecule that will allow binding. There is no step where either the candidate agent or the sequence is immobilized to the support. There are no recited conditions such as reagents required for binding. There are no labels recited within the steps as to allow detection. There are no reagents that recite how to identify the candidate agent. Therefore, the methods are incomplete and lack steps for identifying of a candidate agents. Moreover, the detection step is not sufficient to act as an identification step.

5. Claims 58-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "candidate agents" in the claims is a relative term which renders the claim indefinite. The term "candidate agents" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. IT is unclear what the agents are candidate for. Therefore the metes and bounds of the term are unclear and clarification is required to overcome the rejection.

6. The preamble of claims 58-77 is drawn to a method for identifying agents which bind to SEQ ID NO:1 or amino acids 1 to 357, 443 to 601 and 602 to 784 of SEQ ID NO:1, however the recited steps within the method comprise an addition step and a detection step, thereby identifying said agent as binding to the amino acids. There is no step that correlates the binding of the candidate agent to the amino acids to the identity of the agent. Detecting binding does not equate to identifying the agent. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to identifying an agent.

7. With respect to claims 58, 63, 68 and 73, the addition steps are unclear. It is unclear how a candidate agent is added to an amino acid sequence. Moreover, the claims fail to recite such steps and conditions as to allow said addition, binding and detection. Therefore it is unclear how the method will accomplish identifying an agent, thus clarification is required to overcome the rejection.

8. Claims 62, 67, 72 and 77 are unclear. It is unclear how the nucleic acid agent will be added to the amino acid sequence, and detection of binding and thereby identification will occur. Clarification is required to overcome this rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is

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703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines *JN*  
October 8, 2003

*LS*  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER**